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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

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6/24/99

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/980,400	11/26/97	025	KAUFMAN, D	1645 06/24/99
First Named Applicant	SLEPZIKUSKI,	35 USC 154(b) term ext. :		0 days.

TITLE OF INVENTION BIOLOGICALLY ACTIVE OMERIZED AND MULTIMERIZED POLYPEPTIDE FUSIONS
HAS AMENDED

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	1355CA-00002	530-050,000	UP99 UTILITY	NO	\$1210.00	06/24/99

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability

Application No.

08/980,400

Examiner

Claire M. Kaufman

Applicant(s)

SLEDZIEWSKI ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

1. ☒ This communication is responsive to the interview of June 16, 1999 for the examiner's amendment.
2. ☒ The allowed claim(s) is/are 29-43 and 45-58 to issue as 1-29, respectively.
3. ☐ The drawings filed on _____ are acceptable.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) ☒ All b) ☐ Some* c) ☐ None of the CERTIFIED copies of the priority documents have been
 1. ☐ received.
 2. ☒ received in Application No. (Series Code / Serial Number). 07/347,291.
 3. ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

A SHORTENED STATUTORY PERIOD FOR REPLY to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office Action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be available under the provisions of 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☒ Applicant MUST submit NEW FORMAL DRAWINGS
 - (a) ☐ because the originally filed drawings were declared by applicant to be informal.
 - (b) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review(PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No. 6.
 - (c) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
 - (d) ☐ including changes required by the attached Examiner's Amendment / Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- | | |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>4</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

Art Unit: 1646

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeffrey J. King on June 16, 1999.

The application has been amended as follows:

In the specification, in amendment ~~B~~^V, line 3, replace "divisional" with --continuation--.

In claim ~~39~~, line 5, replace "light" with --heavy--.

Replace claim 45 with the following:

~~45~~⁴⁶ (Twice Amended) A [The] biologically active, heteromultimeric polypeptide fusion, comprising:

a first polypeptide fusion comprising a first non-immunoglobulin polypeptide joined to a first multimerizing protein heterologous to said first non-immunoglobulin polypeptide and a second polypeptide fusion comprising a second non-immunoglobulin polypeptide joined to a second multimerizing protein heterologous to said second non-immunoglobulin polypeptide, wherein said first multimerizing protein and said second multimerizing protein are capable of associating to form a multimer.

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Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Traunecker et al. (Nature, 1989, U) describes a multimer comprising the extracellular domain of CD4 fused to an IgM μ heavy chain which is biologically active (binds HIV gp120, p. 69, second paragraph). However, Traunecker et al. does not anticipate or make obvious the instant invention because CD4 does not normally dimerize or multimerize and the CD4-M μ is a homomeric not heteromeric polypeptide fusion, so that the teachings of Traunecker et al. would not have lead the ordinary artisan to the instant invention. Lasky et al. (US Patent No. 5,098,833, C) issued from application 07/315, 015, to which Capon et al. (US Patent No. 5,116,964, AG) claim priority. However, Lasky et al. do not disclose the concept of multimerizing polypeptide fusions, especially heteromultimeric polypeptide fusions. The closest reference in Lasky et al. is to fusions which include the mature LHR sequence and a heterologous sequence or fusions of LHR to immunoglobulin chains or fragments thereof (col. 7, lines 17-22), which does not address the concept of multimers comprised of polypeptide fusions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

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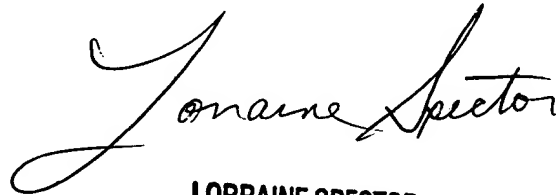
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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.


cmk

June 16, 1999



LORRAINE SPECTOR
PRIMARY EXAMINER

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